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EXAMINER

BLANCO, JAVIER G

ART UNIT

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3774

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

DETAILED ACTION

Response to Amendment

1. Applicant's amendment of claims 1, 6, 11, 12, 13, 14, 17, and 22 in the reply filed on September 5, 2008 is acknowledged.
2. Applicant's cancellation of claim 25 in the reply filed on September 5, 2008 is acknowledged.
3. Applicant's cancellation of claims 14-21 in the reply filed on January 6, 2009 is acknowledged.

Election/Restrictions

4. Applicant's election without traverse of **Group I** (claims 1-13 and 22, drawn to a system for the fixation of a bone fracture) in the reply filed on January 6, 2009 is acknowledged.
5. Applicant's cancellation of claims 14-21 (non-elected Group II and Group III) in the reply filed on January 6, 2009 is acknowledged.
6. Newly submitted claim limitations to claim 11 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: during the Response/Reply filed on October 16, 2006, to the Election of Species Requirement mailed on July 18, 2006, the Applicant elected without traverse **CAP: Species C** (embodied in Figure 2C). Independent claim 11, as newly amended, is drawn to non-elected CAP Species E (embodied in Figure 2E). The specification specifically describes the embodiment of Figure 2E as a planar disk 30 having a central hole 32 and a plurality of surrounding holes 36, each of surrounding holes 36 connected to the central hole 32 via a cut 38.

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Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 11-13 and 22 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Objections

7. Claims 2 and 22 are objected to because of the following informalities:
- a. Regarding claim 2, please substitute “said head component includes a tip, cutting threads and fastening threads” with --said head component includes a tip, **said** cutting threads, and fastening threads--. Appropriate correction is required.
 - b. Claim 22 is not further limiting the new subject matter (e.g. center hole) added to independent claim 11.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(c) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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9. Claims 1-8 are rejected under 35 U.S.C. 102(a) as being clearly anticipated by **HEHL** (WO 00/67652 A2).

Referring to Figures 2-4, 6, 8, and 9, Hehl discloses a system including:

(i) A head component (8) including a tip, cutting threads (see Figures 3 and 4), and fastening threads (as part of the cutting threads);

(ii) A flexible wire (9) having a first end and a second end, and a first interface including a sawtooth configuration (shown in Figures 4, 6, and 9); and

(iii) A cap (5), said cap having a second interface including an inverse sawtooth configuration (shown in Figures 4, 6, and 9). As part of the different embodiments, the second interface of the cap may include an inverse sawtooth (notice the use of singular) configuration on an inner surface of the cap (see Figure 6, any of pawls 16). Hehl disclose that one or more pawls 16 could be used as part of the second interface. Said cap mates/pairs with said second end of said flexible wire by translating (as in a ratcheting system) along said flexible wire over a surface which restricts reverse translational movement (see Abstract). Cap 5 includes a flat surface, a center hole, and cutting/mating threads 20. Excess wire beyond the cap is removed (inherent in order to avoid exposing nearby/adjacent tissue to excess wire/cable, and clearly shown in Figures 3 and 4). A tool (e.g., driver) is capable of being attached to a portion of the head component. A tool/tensioner is used to apply tension the said wire (as in a ratcheting system; and disclosed in the specification of Hehl). The Figures (see Figure 2) and specification clearly disclose the “cutting threads” as capable of insertion into and terminating within an object.

It should be noted that the adjective “flexible” is a broad term. Wire 9 comprises a long, thin shank/body, which will be subject to loads or forces. Said long, thin shank/body will

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inherently flex to some degree when exposed to said loads or forces. Further, Hehl discloses an embodiment of wire 9 as comprising a hollow material (see page 8, lines 22-25), which will inherently decrease its rigidity therefore increasing its flexibility. Additionally, the term “wire” is generally defined as a "slender rod". Wire 9 is in the shape of a slender rod.

While features of an apparatus may be recited either structurally or functionally, claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function. *In re Schreiber*, 128 F.3d 1473, 1477-78, 44 USPQ2d 1429, 1431-32 (Fed. Cir. 1997). A claim containing a “recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus” if the prior art apparatus teaches all the structural limitations of the claim. *Ex parte Masham*, 2 USPQ2d 1647 (Bd. Pat. App. & Inter. 1987). With regards to statements of intended use and other functional statements (e.g., *for facilitating; operable for insertion; configured to translate; to facilitate rotating; for receiving; for applying tension; to apply pressure; etc.*), they do not impose any structural limitations on the claims distinguishable over the device of **HEHL**, which is capable of being used as claimed if one so desires to do so. *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Claims directed to apparatus must be distinguished from the prior art in terms of structure rather than function. *In re Danly*, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA 1959). “[A]pparatus claims cover what a device is, not what a device does.” *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990). Expressions relating the apparatus to contents thereof during an intended operation are of no significance in determining patentability of the apparatus claim. *Ex parte Thibault*, 164 USPQ 666, 667 (Bd. App. 1969).

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Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Dakin et al.** (US 6,368,326 B1; cited in Applicant's IDS) in view of **Cachia** (US 5,893,850 A; cited in Applicant's IDS) and **Fletcher** (US 6,050,998).

Referring to Figures 1-5, Dakin et al. disclose a system including:

- (i)** A head component (e.g., fastener 20) including a tip, cutting threads (20.4), and fastening threads (on the inside surface, or as part of the cutting threads on the outside surface), said "cutting threads" are capable of insertion into and terminating within an object (clearly shown in the Figures);
- (ii)** A flexible wire (cord 22) having a first end and a second end, wherein said first end of said wire mates with said head component, said wire having a first interface (e.g., outer surface; diameter; etc.) along at least a portion of said wire; and
- (iii)** A cap (**first interpretation:** fastener 24, which has cutting threads 24.2, bore 24.3, and interior threads 24.4; **second interpretation:** locking device/screw 28, which has threads 28.1; **third interpretation:** fastener 24 + locking device/screw 28), said cap mates/pairs with said second end of said flexible wire by translating along said flexible wire over a surface which restricts (e.g., by friction, or by crimping) reverse translational movement. Fastener 24 comprises a substantially flat end, a center hole 24.3, and additional openings 24.5, which additional

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openings are capable of expansion. The excess length of the second end of the flexible wire will be removed (inherent in order to avoid exposing nearby/adjacent tissue to excess wire/cable, and clearly shown in Figures 13), but the cap will engage the remaining portion of the second end of the flexible wire. A tool (e.g., driver) is capable of being attached to a portion of the head component (see entire document, particularly column 7, lines 8-14). A tensioner is used for applying tension to said wire (see, for example, Figure 1). A surgical plate is configured to mate with a surface of bone (see Figures).

Notice in Figure 1 how a middle wire portion extends across an interface between a first bone portion 18 and a second bone portion 16. The cap mates/pairs with the second end of the flexible wire. Notice in Figure 13 how a first end of the flexible wire is attached/mated/paired with the head component, and the second end of the flexible wire is attached/mated/paired with the cap.

The excess length of the second end of the flexible wire will be removed (clearly shown in Figures 13). Not only said limitation is inherent (in order to avoid exposing nearby/adjacent tissue to excess wire/cable), but additionally it is well known in the art. For example, Fletcher '998 teaches (see Figure 2, arrow 32; and Figure 9) removing excess length of the second end of a flexible wire (see column 3, lines 23-26) in order to avoid exposing nearby/adjacent tissue to excess wire/cable. Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to have combined the teaching of removing excess length of a flexible wire, as taught by Fletcher, with the system of Dakin et al., in order to avoid exposing nearby/adjacent tissue to excess wire/cable.

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Although Dakin et al. disclose the cap as mating/pairing with the second end of the flexible wire by translating along said flexible wire over an inner surface (e.g., bore) which restricts (e.g., by friction, or by crimping) reverse translational movement, they did not particularly disclose the cap as comprising an inverse sawtooth configuration on said inner surface. However, this is already known in the art. For example, Cachia discloses a system comprising a cap/wire connection wherein the wire comprises a sawtooth configuration (retention structure 44) along at least a portion of said wire, and the cap comprises an inverse sawtooth configuration (retention structure 42) on an inner surface of said cap (see column 4, lines 23-32 and lines 50-67), wherein the cap translates along said wire in order to provide resistance to movement of the cap in the proximal direction relative to the wire (see column 4, lines 23-32 and lines 50-67). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to have combined the teaching of a system comprising a cap and connecting/linking element connection wherein the connecting/linking element (e.g., wire) comprises a sawtooth configuration along at least a portion of said connecting/linking element, and the cap comprises an inverse sawtooth configuration on an inner surface of said cap, wherein the cap translates along said connecting/linking element, as taught by Cachia, with the system of Dakin et al., in order to provide resistance to movement of the cap in the proximal direction relative to the connecting/linking element (e.g., wire).

While features of an apparatus may be recited either structurally or functionally, claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function. *In re Schreiber*, 128 F.3d 1473, 1477-78, 44 USPQ2d 1429, 1431-32 (Fed. Cir. 1997). A claim containing a “recitation with respect to the manner in which a claimed apparatus is

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intended to be employed does not differentiate the claimed apparatus from a prior art apparatus” if the prior art apparatus teaches all the structural limitations of the claim. *Ex parte Masham*, 2 USPQ2d 1647 (Bd. Pat. App. & Inter. 1987). With regards to statements of intended use and other functional statements (e.g., *for facilitating; operable for insertion; configured to translate; to facilitate rotating; for receiving; for applying tension; to apply pressure; etc.*), they do not impose any structural limitations on the claims distinguishable over the device of **Dakin et al.**, which is capable of being used as claimed if one so desires to do so. *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Claims directed to apparatus must be distinguished from the prior art in terms of structure rather than function. *In re Danly*, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA 1959). “[A]pparatus claims cover what a device is, not what a device does.” *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990). Expressions relating the apparatus to contents thereof during an intended operation are of no significance in determining patentability of the apparatus claim. *Ex parte Thibault*, 164 USPQ 666, 667 (Bd. App. 1969).

As noted by the United States Supreme Court, if a person of ordinary skill can implement a predictable variation, § 103 likely bars its patentability. For the same reason, if a technique has been used to improve one device, and a person of ordinary skill would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill. *KSR*, 127 S. Ct. at 1740. "When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product is not of

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innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show it was obvious under 35 U.S.C. 103." *KSR Int'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1742, 82USPQ2d 1385, 1396 (2007).

Response to Arguments

12. With regards to the 102(a) rejection based on **HEHL** (WO 00/67652 A2), Applicant's arguments filed September 5, 2008 have been fully considered but they are not persuasive.

The Applicant's argues: "*Hehl does not disclose or contemplate at least "a head component having cutting threads, said cutting threads operable for insertion into and termination within one of said objects," as recited in independent claim 1. Nor does Hehl disclose or contemplate at least "said cap having a second interface component including a plurality of sawteeth on an inner surface of said cap such that said cap is configured to translate along said wire with certain of said plurality of sawteeth of said cap sliding over certain of said sawteeth of said wire,"*". The Examiner respectfully disagrees.

a. The Figures (see Figure 2) and specification clearly disclose the "cutting threads" as capable of insertion into and terminating within an object. Cap (5) has a second interface, including an inverse sawtooth configuration (shown in Figures 4, 6, and 9). As part of the different embodiments, the second interface of the cap may include an inverse sawtooth (notice the use of singular) configuration on an inner surface of the cap (see Figure 6, any of pawls 16). Hehl disclose that one or more pawls 16 could be used as part of the second interface. Said cap mates/pairs with said second end of said flexible wire by translating (as in a ratcheting system)

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along said flexible wire over a surface which restricts reverse translational movement (see Abstract).

b. It should be noted that the adjective “flexible” is a broad term. Wire 9 comprises a long, thin shank/body, which will be subject to loads or forces. Said long, thin shank/body will inherently flex to some degree when exposed to said loads or forces. Further, Hehl discloses an embodiment of wire 9 as comprising a hollow material (see page 8, lines 22-25), which will inherently decrease its rigidity therefore increasing its flexibility. Additionally, the term “wire” is generally defined as a "slender rod". Wire 9 is in the shape of a slender rod.

13. With regards to the 103(a) rejection based on **Dakin et al.** (US 6,368,326 B1; cited in Applicant’s IDS) in view of **Cachia** (US 5,893,850 A; cited in Applicant’s IDS), Applicant's arguments filed September 5, 2008 have been fully considered but they are not persuasive.

a. The test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

b. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

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c. The Examiner has provided a reason to combine the references that will yield predictable results. The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.

d. As noted by the United States Supreme Court, if a person of ordinary skill can implement a predictable variation, § 103 likely bars its patentability. For the same reason, if a technique has been used to improve one device, and a person of ordinary skill would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill. *KSR*, 127 S. Ct. at 1740. "When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product is not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show it was obvious under 35 U.S.C. 103." *KSR Int'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1742, 82USPQ2d 1385, 1396 (2007).

Conclusion

14. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

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will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Javier G. Blanco whose telephone number is 571-272-4747. The examiner can normally be reached on M-F (9:00 a.m.-7:00 p.m.), first Friday of the bi-week off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Isabella can be reached on (571)272-4749. The fax phone numbers for the organization where this application or proceeding is assigned is 571-273-8300 for regular communications and After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Javier G. Blanco/

Examiner, Art Unit 3774

/David H Willse/

Primary Examiner, Art Unit 3738